

### **REMARKS**

The Examiner has considered Applicant's election with traverse of Group I, claims 1 – 13 in the reply filed on June 12, 2003. Traversal was on the grounds that a search of all the claims would not present an undue burden because the searches for Group I (claims 1 – 13) Group II (claim 14) would overlap significantly. The Examiner has not found Applicant's arguments persuasive. The Examiner considers that Groups I and II require different searches that are not co-extensive, and has deemed the restriction requirement final.

Claims 1 - 14 are currently pending in the application. Claim 14 is withdrawn from consideration. Claim 2 is cancelled. Claims 1, 6, 12 and 13 are currently amended. Claim 15 is new. The amendments and new claim 15 find support in the specification, particularly at pages 5-6. No new matter has been added.

The Examiner has accepted the drawings filed on November 13, 2003.

### **Objections**

The Examiner has objected to the disclosure because it contains embedded hyperlink and/or other form of browser executable code. Applicants have made the appropriate amendment to the specification and request withdrawal of the objection.

### **Claim Rejections**

#### **Claims Rejected under 35 USC §112, first paragraph**

Claims 10 - 13 were rejected under 35 U.S.C. 112, first paragraph as failing to comply with the written description requirement. The Office Action states that the claims are drawn broadly to encompass methods for treating a patient suffering or susceptible to coronary artery disease comprising selecting a patient that has the KL-VS allele and treating the selected patient by administering a therapeutic agent for coronary artery disease. The Office Action states at page 4 that the specification teaches "that therapeutic agents such as nitrate may be administered to the selected patient which has the KL-VS allele." However, the Office Action alleges that the specification does not disclose and

fully characterize methods for treating the selected patient by administering any therapeutic drug. Applicants respectfully traverse the rejection.

First, the claims are not drawn to methods for treating the selected patient by administering **any** therapy or therapeutic agent. The instant claims specify that the therapeutic agent or the therapy is “for coronary artery disease.” Applicants direct the Examiner to page 6 of the specification, which states “a therapeutic agent may be administered to the selected patient, such as a nitrate (e.g. nitroglycerine as may be suitably administered sublingually, or an amyl nitrate, isosorbide dinitrate or pentaerythritol tetranitrate).” Nitrates, as taught by the specification represent a genus of therapeutic agents. Further at page 6, the specification teaches specifically what lifestyle changes or surgical interventions, as forms of treatment.

“The selected patient is then treated for coronary artery disease...lifestyle change such as to eliminate or reduce smoking, weight loss, increase or aerobic exercise and the like; or surgical intervention such as coronary arterial bypass surgery.”

Applicants assert that the application reasonably conveys to the skilled artisan that the inventors had possession of the claimed subject matter insofar as having sufficiently described distinguishing identifying characteristics of the therapeutic agents or the therapies for coronary artery disease.

Applicants therefore respectfully request that the rejection be reconsidered and withdrawn.

#### Claims Rejected under 35 USC §112, second paragraph

Claims 1 - 13 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to point out and distinctly claim the subject matter which the applicant regards as the invention. Applicants respectfully traverse the rejection.

The Examiner argues that claims 1, and 3 – 8 are indefinite in that the goal of the method and the final step do not agree. Applicants have amended the claims and submit that the claims are allowable.

The Examiner argues that claims 6 – 8 are indefinite because the claims do not recite step (c) of the claimed method in a positive, active fashion. The claims have been

amended as per the Examiner's suggestion. Applicants thus submit that the claims are allowable.

The Examiner argues that claims 12 – 13 are indefinite because it is not clear if the surgery and lifestyle change are the treatment or if these are done in addition to the treatment. Claims 12 and 13 are dependent from claim 10, which recites a method for treating a patient suffering or susceptible to coronary artery disease, and further recite what the treatment is, e.g. "a lifestyle change for treatment (claim 13). Thus, it is not clear how the claim is indefinite. However, solely to obviate the rejection, Applicant has amended the claims 12 and 13 to recite, e.g. "a lifestyle change for treatment of coronary artery disease."

Applicants respectfully request that the rejection of the claims on the basis of 35 U.S.C. 112, second paragraph be reconsidered and withdrawn.

#### Claims Rejected under 35 USC §102 (b)

Claims 1 – 3, 5 and 9 have been rejected under 35 USC §102 (b) as being anticipated by Arking et al. (PNAS). The Examiner argues that regarding claim 1, the Arking reference teaches a method comprising isolating DNA from a patient and analyzing the DNA to detect the presence of the KL-VS allele. Applicants respectfully disagree and traverse the rejection.

Claim 1, as amended, recites the steps isolating and analyzing the DNA to detect the presence of the KL-VS allele, and further comparing the presence of the KL-VS allele in the patient to a control, wherein detection of the KL-VS allele indicates the patient is predisposed to develop coronary artery disease. Arking et al. do not address all of the limitations set forth in claim 1, specifically, Arking et al. do not teach a method for determining predisposition to coronary artery disease through detection of the KL-VS allele. The Examiner points out that Arking et al. use SSCP analysis and DNA sequencing to identify the KL-VS allele. However, Arking et al. do not associate the presence of the KL-VS allele with coronary artery disease, or a disposition for coronary artery disease. In their analysis of KL-VS expression, Arking et al simply compare expression between populations, they do not relate allelic expression to any specific age-related phenotype.

Thus, Applicants respectfully request withdrawal of the 35 U.S.C. §102 (b) rejection and reconsideration of the instant claims.

Claims Rejected under 35 USC §103

Claims 4 and 6 – 7 were rejected under 35 USC §103 (a) as being unpatentable over Arking et al. in view of Francis et al (US Patent 6210877). Applicants respectfully traverse the rejection.

As indicated above, the Arking reference provides no teaching or suggestion that the KL-VS allele is associated with a predisposition to develop coronary artery disease, nor does it provide a method for determining a patient's predisposition to develop coronary artery disease comprising a method as taught in the instant claims. Francis et al. does not cure this defect of Arking. As such, Applicants respectfully request withdrawal of the 35 U.S.C. §103 (a) rejection and reconsideration of the instant claims.

Claim 8 was rejected under 35 USC §103 (a) as being unpatentable over Arking et al. in view of Francis et al (US Patent 6210877) and further in view of Levitt (US patent 5,908839).

As indicated above, the Arking reference provides no teaching or suggestion that the KL-VS allele is associated with a predisposition to develop coronary artery disease, nor does it provide a method for determining a patient's predisposition to develop coronary artery disease comprising a method as taught in the instant claims. Nothing in either Francis or Levitt cures this defect of Arking. As such, Applicants respectfully request withdrawal of the 35 U.S.C. §103 (a) rejection and reconsideration of the instant claims.

Claims 10 – 13 were rejected under 35 USC §103 (a) as being unpatentable over Arking et al. in view of Bockow et al. (US 2002/0055539).

As indicated above, the Arking reference provides no teaching or suggestion that the KL-VS allele is associated with a predisposition to develop coronary artery disease, nor does it provide a method for determining a patient's predisposition to develop coronary artery disease comprising a method as taught in the instant claims. Nothing in Bockow et al. cures this defect of Arking. As such, Applicants respectfully request withdrawal of the 35 U.S.C. §103 (a) rejection and reconsideration of the instant claims.

For the reasons provided, Applicant submits that all claims are allowable as written and respectfully requests early favorable action by the Examiner. If the Examiner believes that a telephone conversation with Applicant's attorney/agent would expedite prosecution of this application, the Examiner is cordially invited to call the undersigned attorney of record.

A request for an extension of time is enclosed, and although it is not believed that no additional fees are needed to consider this submission, the Examiner is hereby authorized to charge our deposit account no. 04-1105 should any fee be deemed necessary.

The Director is hereby authorized to charge any credits or deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 04-1105, under Order No. 58878 (71699).

Respectfully submitted,



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Date: October 6, 2006

Customer No.: 04-1105